K080667

Summary of Safety and Effectiveness
VariAx™ Distal Radius Torx Screws

MAR 19 2008

Proprietary Name:	VariAx™ Distal Radius Torx Screws
Common Name:	Bone plates and screws
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Device Product Code:	87 HRS
For Information Contact:	Danielle Hillman, Regulatory Affairs Associate Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6365 Fax: (201) 831-6038
Date Summary Prepared:	March 7, 2008

Description:

The VariAx™ Distal Radius Torx Screws in combination with the plates from the Stryker® Leibinger Universal Distal Radius System are designed to treat various types of fractures of the distal radius.

Intended Use:

The modifications do not alter the intended use of the predicate system as cleared in the referenced premarket notifications. The subject and predicate devices are available both sterile and non-sterile intended for use in fracture fixation of the distal radius. The indications for use for the VariAx™ Distal Radius Screws are provided below.

Indications for Use:

Stryker® Leibinger Universal Distal Radius System is intended for use in internal fixation of the small bone fractures, primarily including distal radius fractures. Examples of these distal radius fractures include compression fractures, intra-articular and extra-articular fractures, displaced fractures and surgical reduction. This system can be used for palmar, dorsal, or orthogonal application.

Substantial Equivalence:

The subject VariAx™ Distal Radius Screws share the same intended use and design concepts as that of the currently available Stryker® Leibinger Universal Distal Radius System and Stryker® Foot System. Mechanical testing demonstrated comparable mechanical properties to the predicate components and is substantially equivalent to these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Howmedica Osteonics Corp.
% Ms. Danielle Hillman
325 Corporate Drive
Mahwah, NJ 07430

MAR 19 2008

Re: K080667
Trade/Device Name: VariAx Distal Radius Torx Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: March 7, 2008
Received: March 10, 2008

Dear Ms. Hillman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K080667

Device Name: VariAx™ Distal Radius Torx Screws

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Janita D

(Division Sign-Off)

for **Division of General, Restorative, and Neurological Devices**

510(k) Number K080667